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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,507	04/17/1997	TADAMITSU KISHIMOTO	53466/201	8301

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>08/817,507</b>	Applicant(s) <b>Kishimoto</b>
	Examiner <b>Karen Canella</b>	Art Unit <b>1642</b>
		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)  Responsive to communication(s) filed on \_\_\_\_\_.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4)  Claim(s) 15 and 24-28 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 15 and 24-28 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	20) <input type="checkbox"/> Other: _____

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***Response to Amendment***

1. Claim 15 has been amended. Claims 15 and 24-28 are pending and under consideration.

***Claim Rejections Withdrawn***

2. The rejection of claims 15, 24, 26 and 27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

***Claim Rejections Maintained.***

3. The rejection of claims 15 and 24-28 under 35 U.S.C. 103(a) as being unpatentable over Emilie et al (Blood, 1994, Vol. 84, pp. 2472-2479) in view of Sato et al (Cancer Research, 1993, Vol. 53, pp. 851-856) is maintained. Claims 15 and 24-28 are drawn in part to a method of treating a human subject suffering from cachexia comprising administering a therapeutically effective amount of the humanized PM-1 antibody, said antibody blocking signal transduction from IL-6 by to the IL-6 receptor. Emilie et al teach the alleviation of the symptoms of cachexia in human patients by a method comprising the administration of an antibody which binds to IL-6. Emilie et al do not teach the administration of antibodies to the IL-6 receptor. Sato et al teach the humanized PM-1 antibody which binds to the IL-6 receptor, and the administration of said antibody to treat interleukin-6-dependent tumor growth, wherein the administration of said antibody is effective in blocking signal transduction by IL-6. It would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method taught by Sato et al as a method of treating cachexia in a human patient. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Sato on the in vitro efficacy of the humanized PM-1 antibody in blocking of IL-6.

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mediated signal transduction in human cells by binding to the IL-6 receptor, and the teachings of Emilie et al preventing the activation of the IL-6 receptor by binding the ligand for the IL-6 receptor with an anti-IL-6 antibody.

Applicant has amended claim 15 to read on a method of treating a patient suffering from elevated blood levels of ionized calcium accompanied by cachexia in order to ~~boviate~~ this rejection. However, Emilie in view of Sato teach the administration of the PM-1 antibody for the treatment of cachexia and it would be inherent in the method that it would treat the patient suffering from elevated levels of ionized calcium accompanied by cachexia.

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
December 17, 2001

*[Handwritten Signature]*  
KAREN A. CANELLA  
PATENT EXAMINER  
DECEMBER 17, 2001